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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,520	01/21/2004	David I. Freed	06530.0309	1095

22852 7590 08/23/2005

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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/760,520

Applicant(s)

FREED, DAVID I.

Examiner

Matthew J. Kasztejna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-54 and 56-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-54 and 56-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/21/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, 9-18, 22-30, 33-40, 42-44, 46, 47-52, 54, 56, 58-63 and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,682,599 to Konomura.

In regards to claims 1, 28, 47-52, 54, 56, 58-63 and 65-68, Konomura discloses a medical device comprising: a proximal handle; an elongated member 2 having a proximal end, a distal end, and a lumen there between, the proximal end being coupled to the proximal handle, the elongated member being sufficiently flexible to traverse through tortuous anatomy of a patient's body; an end effector 6 proximate the distal end of the elongated member, actuation of the proximal handle 14 causing the end effector to perform a medical procedure; and a distal member configured to open and substantially close the distal end of the lumen, the distal member defining a flow path such that, when the distal member substantially closes the distal end of the lumen, the flow path enables a flow communication between the lumen and an outside of the elongated member (se Figs. 1 and 2, and Col. 4, Lines 1-14). The apparatus of Konomura is inherently capable of performing the recited method steps.

In regards to claim 2, 35, Konomura discloses a medical device wherein the flow path defined by the distal member has a cross-sectional flow area less than a cross-sectional flow area of the lumen (see Fig. 2)

In regards to claims 3-4, 36, Konomura discloses a medical device including a port 10 which is in fluid communication with the lumen and comprises a fluid supplying member for supplying fluid to the port (see Col 3, Lines 20-25).

In regards to claim 8, 38, Konomura discloses a medical device wherein the end effector includes a snare loop 6 (see Col. 3, Lines 8-16).

In regards to claims 10-13, 37, Konomura discloses a medical device wherein the distal member includes a sealing member 7. At least a portion of the distal member has a frusto-conical shape for substantially closing the lumen. The distal member includes a base portion and a head portion, the base portion having an outer diameter substantially the same as an inner diameter of the lumen, the head portion having an outer diameter greater than the inner diameter of the lumen. Also, the distal member includes a plate member having an outer diameter substantially the same as the inner diameter of the lumen (see Col. 3, Line 64 – Col. 4, Line 13).

In regards to claims 14-15, Konomura discloses a medical device wherein at least a portion of the flow path has a cross-sectional flow area smaller than that of at least one of an inlet and an outlet of the flow path (see Col. 4, Lines 36-68).

In regards to claims 16-18, 39-40, 42-44, Konomura discloses a medical device wherein the distal member connects to the end effector at a distal end of the end effector and the distal member is movable relative to the lumen and is configured to

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substantially close the lumen when the end effector retracts (see Fig. 1 and Col. 4, Lines 1-14).

In regards to claims 22-27, Konomura discloses a medical device wherein the distal member is fixedly connected to a distal end of the elongated member and wherein the flow path has an inlet opening in a direction transverse to a axis of the annular body and an outlet opening in a direction substantially parallel to the axis of the annular body (see Fig. 6)

In regards to claims 28-30, 34, Konomura discloses a medical device wherein the handle includes a stationary part 15 and movable part 14. Further comprising a control member 5 having a proximal end coupled to the movable part and a distal end coupled to the end effector so that actuation of the movable part relative to the stationary part enables movement of the end effector for performing the medical procedure (see Fig. 1 and Col. 3, Lines 26-47).

In regards to claim 33, 46, Konomura discloses a medical device wherein the distal member defines a plurality of flow paths (see Fig. 5)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 5,599,324 to McAlister et al.

In regards to claims 5-7, Konomura discloses a medical device but is silent with respect to a fluid supply member (syringe) for supplying fluid to the port, an interlocking member and fluid chamber sealed from a portion of the handle. McAlister et al. teach of an analogous device in which a physician can attach a syringe or other device to the second entry port 31 and force a contrast agent through the passage 35, the central volume 33 and the lumens 23 and 24 in parallel to be discharged where the lumens 23 and 24 exit the distal end 17. The seals formed between the tube 36 and the handle 12 and between the tube 36 and the catheter tube 11 around the guidewire 22 assure isolation of the guidewire lumen 22 (see Col. 5, Lines 13-22). It would have been obvious to one skilled in the art at the time of the invention to include a fluid supply assembly in the device of Konomura so if it is necessary to relocate the distal tip 20, there is no need to remove the guidewire as taught by McAlister et al.

Claims 19-21 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 5,947,978 to Holsinger.

In regards to claims 19-21 and 41, Konomura discloses a medical device but is silent with respect to the distal member connected to the proximal end of the end effector. Holsinger teach of an analogous device having a distal member 30 fixedly secured to the actuator 18 and free end 32 for insertion into a patient having flanges 74

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to secure the distal member to the elongated member (see Fig. 12). It would have been obvious to one skilled in the art at the time the invention was made to include a fixedly secured distal member in the apparatus of Konomura in order to prevent objects and fluids from entering the lumen, as taught by Holsinger. The apparatus of Konomura would then be inherently capable of performing the recited method steps.

Claims 31-32, 45, 53 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,682,599 to Konomura in view of U.S. Patent No. 5,575,694 to Hawkins et al.

In regards to claims 31-32, 45, 53 and 64 Konomura discloses a medical device but is silent with respect to an electrical connector for receiving cautery current from a power supply source. Hawkins et al. teach of an electrical connector for attachment to a cauterizing endoscopic snare (see Col. 2, lines 57-67). It would have been obvious to one skilled in the art at the time the invention was made to include such an electrical connector in on the device of Konomura in order to provide the snare loop with an electrical current and therefore assist in surgical procedures, as taught by Hawkins et al. and is well-known in the art. The apparatus of Konomura would then be inherently capable of performing the recited method steps.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK

ML

8/10/05



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